ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Systems and Procedure Packs sterilised in accordance with the manufacturer's instructions, Article 22(3))

No. G14 012974 0629 Rev. 00

Certificate Holder: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

SRN System and Procedure Pack Producer: DE-PR-000005115

The Certification Body of TÜV SÜD Product Service GmbH certifies that the Certificate Holder has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The involvement of the notified body is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G14 012974 0629 Rev. 00

Report No.: 713217552

Valid from: 2022-05-13
Valid until: 2027-05-12

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-05-13

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Systems and Procedure Packs sterilised in accordance with the manufacturer's instructions, Article 22(3))

No. G14 012974 0629 Rev. 00

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4039239000002061ZW
Intended Purpose:	Set for Central Venous Catheterization
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40392390000020592E
Intended Purpose:	Set for Central Venous Catheterization
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40392390000020582C
Intended Purpose:	Set for Central Venous Catheterization
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	403923900000206529
Intended Purpose:	Multipack for drug admixture
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	403923900000206427
Intended Purpose:	Multipack for drug admixture
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	403923900000204829
Intended Purpose:	Set for Epidural Anesthesia
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40392390000020492B
Intended Purpose:	Set for Combined Spinal & Epidural Anesthesia
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	403923900000205628
Intended Purpose:	Set for Peripheral Nerve Blocks
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	403923900000206325
Intended Purpose:	Set for Specific or General Applications

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Systems and Procedure Packs sterilised in accordance with the manufacturer's instructions, Article 22(3))

No. G14 012974 0629 Rev. 00

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4039239000002060ZU
Intended Purpose:	Set for Specific or General Applications

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40392390000020572A
Intended Purpose:	Set for Regional Anesthesia Applications

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4039239000002050ZR
Intended Purpose:	Set for Regional Anesthesia Applications

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	403923900000204727
Intended Purpose:	Set for Spinal Anesthesia

The validity of this certificate depends on conditions and/or is limited to the following: -

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®